Summary of Notes from the MassDPH-MassDEP Joint Summit on
Pharmaceuticals and Personal Care Products in the Massachusetts Environment
held on June 5, 2008

Disclaimer: These notes reflect the main points made by each speaker. MassDEP appreciates the openness with which all of the attendees discussed the topic, but does not endorse as fact any particular statement by non-MassDEP participants. Furthermore, MassDEP considers the points made as suggestions and recommendations and not necessarily action items.

Purpose of Summit: The primary purpose of this Massachusetts summit on PPCPs in the environment was to assemble the decision-makers from government, academia, private industry and citizen groups, to begin to develop a strategy to evaluate the impact of these compounds on human health and the environment as a prelude to identifying potential solutions.

Goals of Summit: The goals of the first Summit were to:

- Provide a forum for discussion of the issues associated with environmental pharmaceuticals,
- Identify the issues and potential problems associated with PPCPs in the environment,
- Identify potential solutions to the problems,
- Identify an initial strategy to effectively and efficiently achieve the solutions

MEETING NOTES

Dave Noonan, Massachusetts Department of Environmental Protection (MassDEP) gave the introduction and thanks to all participants.

Laurie Burt, Commissioner of MassDEP:

- Since 2006, MassDEP has been a leader on this issue through its emerging contaminants workgroup which identified Pharmaceuticals and Personal Care Products (PPCPs) as contaminants of emerging concern. The emerging contaminants workgroup has been working to identify and develop information and policies on contaminants not currently regulated by the federal government or Massachusetts (MA).
- MassDEP has embarked on a study in partnership with UMass-Amherst and EarthTech to determine occurrence of selected PPCPs, the effectiveness of commonly used disinfection processes, and whether the treatment processes create metabolites.
- USGS is conducting watershed assessments nationally, including one in the Merrimack River Valley (Lowell drinking water treatment facility), to determine the removal effectiveness of drinking water treatment systems. Goals include identification of assessment priorities including where water supplies are most vulnerable.
- This issue lies at the intersection of science and public policy: we need to know more, but science is not enough. Caution is warranted, but panic is not. Where are the points of influence: drinking water treatment, drug design and disposal, and wellhead protection and siting. This requires coordinated effort among all stakeholders. National support and national standards are necessary.

Suzanne K. Condon, Associate Commissioner of Massachusetts Department of Public Health (DPH) and Director of the Bureau of Environmental Health:

- DPH deals with the public's wide range of questions
- We can measure contaminants at very low levels, but it is more difficult to determine the effects at these very low levels. We know enough to know that something needs to be done.
- Health data is extrapolated from animal models, but what does this mean for compounds designed specifically for human effects.
- Endocrine impacts on marine life (24/7 exposure) have been identified; what about more limited exposure for humans? We know that information is available, and the public will make connections and be concerned.
- DPH is grateful for the science MassDEP has done.
- DPH is dealing with the related household sharps disposal issue, and some of the same mechanisms may become available for other drug disposal.
- A rational and prudent approach is needed, no hysteria, and national leadership is also needed at all levels to avoid redundancy.

The emcee, Dr. Nicholas Anastas (MassDEP) opened a set of 5-minute presentations by a variety of stakeholders. PPCPs have been in the environment for some time, some have been around for decades, but it is only now that we have the measurement technology to reach the part per trillion levels that show these compounds to be ubiquitous. This issue is multidisciplinary, and for solutions to be achieved, the discussion needs to start now. He also highlighted this as both a science and a public policy issue with a variety of drivers and barriers. Nick observed that science drives policy and sometimes, vice versa.

The five-minute speakers:

David Reckhow, Ph.D., UMass-Amherst:

- He is the lead for UMass research project with MassDEP and EarthTech as partners. The study, titled "Investigation of Treatment Effectiveness on Selected Endocrine Disrupting Compounds and PPCPs in Drinking Water," is designed to evaluate the presence of these compounds in the raw and treated water of volunteer water suppliers (including the Massachusetts Water Resources Authority (MWRA) as well as bench-scale testing of existing and new treatment technologies for removal of these compounds.

Bob Rio, Associated Industries of Massachusetts (AIM):

- This is the second environmental working group that AIM has participated in on emerging contaminants, the first being perchlorate.
- Does not want additional regulations. AIM believes that existing regulations and best management practices can be used.
- He mentioned that a Walgreens in his home town accepted unwanted medications from consumers; household hazardous waste days could serve as well.
- Drugs that pass through the body are a different issue that will need a different approach.

Chris Waldron, Ph.D., United States Geological Survey (USGS):

- USGS has been involved in this issue for over ten years.
- Sub-parts per million (ppm) measurement of anthropogenic organic compounds (AOCs) is recent; the compounds may have been around for a long time.
- By the late 1990s, USGS started analyzing for >100 AOCs in environmental samples (ground and surface waters) including some in Massachusetts.
- In 1999-2000, a national sampling effort was taken to sample 139 waterbodies, including 6 in MA (parts of the Charles and the Merrimack Rivers). Ninety-five AOCs were monitored, including 29 pharmaceuticals. Eighty percent of tested samples had at least one AOC, and 40 of the 95 were found in a waterbody in MA. Not all the surface waters tested are drinking water sources.
- The next phase targeted source waters for drinking water: 72 sources, 6 in MA, including the Merrimack and wells in Assabet. Thirty compounds were detected, including acetaminophen and antibiotics.
- The third phase looked at raw and finished waters nationally, including MA systems in the Connecticut River Valley for volatile organic compounds (VOCs) and other AOC including PPCPs. Nothing was detected in the Connecticut River Valley samples.
- Additional work comparing raw water and treated waters is ongoing.
- USGS, with the Barnstable County Department of Health and the Environment, examined treated wastewater outflow and impact on groundwater drinking water supplies.
- Information on these studies is available on the USGS website.

Richard Williams, Ph.D., *Ph*arma and Pfizer:

- He is involved on the research side at Pfizer and has been working on these issues since 1992. He has been involved with a pharmaceutical task force since the late 1990s to look at issues such as disposal.
- The detection ability is new, not the presence of drugs.
- He stated that the majority of the pharmaceuticals in water come through excretion.
- His task force has developed a model of the US drinking water sources, publically owned treatment works (POTWs), etc. to evaluate the potentials for contamination from PPCPs.
- He cited research that modern sanitary landfills protect the environment from these compounds.
- He also mentioned the United States Fish and Wildlife Service SMAR$_x$T disposal program.
- Richard said that there was no evidence of adverse effects on human health, as seen in a database of research papers with 347 papers on the subject, evaluating >65,000 analyses. There are about 12,000 papers examining potential aquatic effects.

Ray Jack, Massachusetts Water Works Association (MWWA):

- He teaches wastewater and environmental health at college, and also represents water system operators and local issues.
- He spoke about the development of the United States Environmental Protection Agency (EPA), the Clean Water Act, and the Safe Drinking Water Act.
- The PPCP issue is not only about drinking water treatment, but also about wastewater treatment.

- He concurred with others on low-level detections, and unknown fate and transport, as well as the sensationalism in the news. This becomes a public health concern and erodes confidence in drinking water.
- It is important to pick the battles we can with resources we have. EPA already has a list of contaminants that they could potentially regulate in the future (the third Contaminant Candidate List (CCL3).
- If we concentrate on removing PPCPs, what other hazards are we ignoring? Who will pay?
- Three components: scientific, societal and political.
- MWWA supports this summit, but wants other sources of potential exposure (e.g., food), explored as well. EPA should be involved.

Charles Tyler, Mass Water Pollution Control Association:

- Shares the same concerns as the MWWA. Wastewater operators already share responsibility for the finished product going to drinking water.
- He is concerned about unfunded mandates. Also, public perception based on misinformation could harm the industry.
- People are getting the message about not flushing drugs but more education is needed for nursing homes, assisted living and hospices.
- Aquatic health is an issue, as well as potential human health.
- People are interested and have been asking questions about this issue during the public tours of Deer Island.

Jim Shine, Ph.D., Harvard School of Public Health:

- He has studied transport, fate and toxicology, but is more involved in asking questions not answers.
- He has the opportunity to work with a variety of other disciplines: epidemiology, economics, etc. and this issue is highly multidisciplinary.
- It's not a surprise to find PPCPs in water due to new measurement but what does it mean for health and the environment?
- Are we looking at the right compounds? Compounds have all sorts of variables, impacting fate and health effects.
- Scoping questions are needed: "what is the right approach", "what are the priorities", "what are the effects on humans?"
- The Harvard School of Public Health is involved in looking at existing data to estimate loading of PPCPs and toxicology.
- Swiss studies on molecular architecture are being used to estimate persistence, toxicity to determine the risk of exposure and risk to health.
- Medical doctors need to be involved because they have studied the target and known side effects of PPCPs.

Janet Bowen, EPA Region 1:

- Works with the hospital sector on pollution prevention and sustainability and is new to the PPCP subject. She has a 1200+ member New England hospital e-mail list.
- In April 2006, EPA published "Managing Pharmaceutical Waste, a 10-step blueprint" with Best Management Practices (BMPs) for hospitals. The guide will be updated in a few months.

- About 5% of the 3000 plus pharmaceutical compounds stocked in a hospital are Resource Conservation and Recovery Act (RCRA) hazardous wastes (listed P or U waste, or characteristic). Another ~10% should also be managed as hazardous wastes.
- PPCPs are on EPA's agenda, may include revision of the universal waste code.
- EPA is also working on a health services industry study survey which includes disposal issues. This draft for public comment is due out in August of 2008.
- The Healthcare Environmental Resource Center (HERC) has a resource webpage, launched April 2006, with information on PPCPs. EPA also has its own PPCP page at www.epa.gov/ppcp.
- EPA has also sponsored grants for take-back programs in places like Maine and has given grants to the New England Recycling Council (NERC). EPA looks forward to working with this summit group.

Steve Estes-Smargiassi, MWRA:

- MWRA tested raw water for target PPCPs and did not find anything, perhaps due to source control and protection.
- Risk communication needs to be more active in this process.
- The American Water Works Association has been investigating this issue for several years.

Nick Anastas introduced some framework for the discussion. The lifecycle of PPCPs include the following steps, with some examples of how the process can be made more sustainable:

PPCP Life Cycle ⟶
DESIGN→MANUFACTURE→DISTRIBUTION→DISPENSE→DISPOSAL

- Design – "Green Pharmacy", green chemistry
- Manufacturing – biodegradable packaging, pollution prevention
- Distributing
- Dispensing – per patient, Nick introduced the idea of "pill economy" where every pill that is prescribed is taken
- Disposal –where and how?

There is also an environmental lifecycle:

Environmental Life Cycle
Occurrence→Fate and Transport→Hazard→Analysis→Treatment

- Occurrence: how to test, where to test, what to test for?
- Fate and transport: what are breakdown products and are they more toxic/persistent than original product?
- Hazard
- Analysis
- Treatment: For example, triclosan and triclocarban (antimicrobials added to a variety of consumer products) can end up in the sludge or affect the performance of a sequencing batch reactor. What does this mean for land application?

Pharmaceuticals in the Environment (PIE) Strategy	Drivers	Barriers
Science	-Education -Pharmaceutical companies have risk data (< 1 part per billion (ppb))	-Where will resources come from to measure it? -Can we measure it? -Can we ever know cumulative impacts?
Policy	-5% versus 95% (flushing versus excretion)? -Push towards green chemistry -40% of MA on septic -Public needs to understand their own personal impact and contribution	-Resources -Locations -Police involvement? -Drug control programs -Pharmacies need incentives

Other lifecycle issues:

- Lifecycle has to also include the decision to make/use the product.
- A mail-back bag could be included with every prescription.
- The Swedish system gives an eco grade to each medication to assist with prescribing decisions. Each medication in the formulary is rated on toxicity and persistence; Australia has similar guidance.

Education and Public Perception:

- Public education is needed to guide decision to market or use products with PPCPs compounds. Public health nurses and other health care providers can help educate the public. Doctors, pharmacists, etc. should also be educated – can we get this subject taught at pharmacy, nursing and medical schools? If these curricula are full, can pharmacists have education campaigns in-house once a week/month?
- There needs to be grassroots effort for the public to educate themselves about contaminants in water. Educate basin "stewards" and get the word out.
- We have to make sure we're not contradicting our own advice, e.g., on stockpiling medications for an emergency.
- Message must be simple and consistent. Conflicting messages (e.g., flush, don't flush) are confusing and demoralizing. The toilet-to-tap issue makes some people uncomfortable.
- People need to be educated that the toilet is not a trashcan.
- The message has to be tested for accuracy and reaction. We don't want people to think the water is unsafe. There can be unintended consequences with saying "here's how we're going to remove this." The message must be clear, consistent and on target. MassDEP and DPH need to make sure it is clear why. Studies get in the press and this puts water suppliers, MassDEP, DPH on defensive. This needs to be a transparent process.
- What already exists, and what messages are already out there? Some information is on www.teleosis.org, a green health care institute.
- Vulnerability assessments should be performed to find out what is influenced by effluent, etc. Keep a message that is clear and not alarming.

- Mind the "yuck" factor – people don't want to have drugs in the water because of how they got there.
- The "nocebo" effect exists. Public perception can lead to real symptoms. MassDEP's website has a lot of information, but answering "is it safe" is tough.

Drug Take Back Options and Barriers:
- About 10% of drugs are controlled substances. Take-back programs need clear standards and procedures; there are many barriers including United States Drug Enforcement Administration (DEA) requirements. Can DPH lead on this?
- The DEA has to be brought to the table as anti-abuse policies are a barrier to drug collecting, etc.
- Can pharmacists be made "agents of the law"?
- Where can we get the most effect for the fewest resources?
- Flushing of drugs is at least part of the problem, and may be relatively easy to address.

Ecological Effects:
- Effects in wildlife are probably more serious than those in humans.
- "Pseudo persistence" can exist for a degradable compound where it is continuously discharged; environmental receptors are subject to exposure 24/7.
- Unused meds are only ~5% of what ends up in the wastewater. We should do the right thing with take-back programs but not lose sight of the biggest source, excretion. The 5% figure needs more research; however, much of the problem is with excreted drugs and drug byproducts.
- Which are more potent or toxic? Does metabolism create less or more harmful substances? Information is available to show that sometimes it goes either way; we may not be able to test for all breakdown products.

Drug development and business issues:
- Green chemistry principle #10 – design for degradation – is relevant, but drugs are designed to have a specific effect. Pharmaceutical development is a business.
- Medication also saves and improves lives.
- For profit pharmacies lack the resources as well; this should not be a burden on them.
- Keep the burden off people involved with water and wastewater. People assume water is clean, focus the message on fish/ecological effects. Don't test the drinking water if you can avoid it. Don't repeat the way MassDEP dealt with perchlorate.

Indicators or Surrogates, biomonitoring:
- Should MassDEP focus on indicators (e.g., caffeine, acetaminophen)?
- Likely analytes that are found everywhere include caffeine, Tylenol, tegretol and others. Caffeine itself is everywhere and may not be a reliable tracer. Acetaminophen is a much more reliable indicator of effluent.
- *Ph*arma Supports the use of surrogates for tracking of PPCPs.
- The use of familiar compounds, such as "Tylenol" may assist public perception, since everyone takes this drug, and they are comfortable with it (lower perceived risk). What about dental whiteners for this purpose or statins?

- DPH has to explain the NHANES data often - the biomonitoring was done without clear direction from CDC as to what would be done with it and what it meant.

Impact on other MassDEP programs:
- Wastewater recharge and reuse regulations.
- Private wells and septic systems.

Other substances:
- Radioactive medical therapies
- Non-drug PPCPs such as shampoos, sunscreens (direct discharges to waterbodies through swimming)
- Other household toxics (e.g., paintbrushes)
- The toxicology of mixtures.
- The whole philosophy has to change, the Safe Drinking Water Act in 1974 looked at what they could measure, and maybe did not focus on the most hazardous items. Are things toxic and do they exist, otherwise don't focus on them.

MWRA:
- There are good messages to give, including "source water protection works." This may not be practical nationwide.
- MWRA developed monitoring plan with assistance from MassDEP.

Additional Stakeholders who should be involved:
- Agriculture and veterinary groups need to be included, as a significant fraction of antibiotics are used for livestock. There was an EPA Clean Med Conference which included agricultural medications.
- US CDC needs to be involved. DPH can help get them involved.
- Need to get input from medical consultants. Medical expertise would be valuable in maintaining transparency on this whole issue as well as technical advice on targets of drugs.
- Bring the DPH Food Protection and other related programs into the discussion as well as other MassDEP programs.
- Other utility representatives would be valuable such as: Upper Blackstone (Tom Walsh), Springfield Water and Sewer (Joe Superneau), South Essex Sewerage District, Charles River Pollution Control District, and/or some smaller utilities. Include utilities that discharge into freshwater destined for some type of reuse.
- Senator Barbara Boxer's group
- Health Care Without Harm
- Media Consultant (e.g., Susan Santos)
- Someone from Maine's take back program. Input/advice from other states.
- What about the European Union's Registration, Evaluation, Authorization and Restriction of Chemical substances (REACH)? Does the Swedish system work?

List of Attendees:

Ruth Alfasso (MADPH)

Nicholas Anastas (MassDEP)
Kathleen Baskin (Executive Office of Energy and Environmental Affairs—EOEEA)
Meg Blanchet (DPH)
Janet Bowen (EPA Region 1)
Laurie Burt (MassDEP)
Michael Celona (DPH)
Suzanne Condon (DPH)
Steve Estes-Smargiassi (MWRA)
Steve Hughes (DPH)
Ray Jack (Mass. Water Works Association)
Kathy Keough (Mass. College of Pharmacy and Health Science)
Staff person from Peter Koutoujian's office (State Representative)
Stephen Mulloney (Biotech Council)
David Noonan (MassDEP)
Roy Petre (DPH)
Vandana Rao (EOEEA)
Brent Reagor (Mass. Health Officers Association)
David Reckhow (University of Massachusetts—Amherst)
Rick Reibstein (Office Technical Assistance)
Staff person from Pamela Resor's office (State Senator)
Bob Rio (Associated Industries of Mass.)
Carol Rowan-West (MassDEP)
Caleb Slater (Mass. Department of Fish and Game)
James Shine (Harvard School of Public Health)
Staff person from Frank Smizik's office (State Representative)
Chris (Marcus) Waldron (USGS)
Charles Tyler (Mass. Water Pollution Control Association)
Donna Williams (Blackstone River Coalition)
James White (Mass. Environmental Health Association)
Charlotte Stepanian (Mass. Public Health Nurses)
Richard Williams (Pfizer)